RL/REG-97-07
Revision 0
6/25/97

Guidance for the Review of TWRS Privatization Contractor Integrated Safety Management Plan Submittal Package

June 1997

Office of Radiological, Nuclear, and Process
Safety Regulation for TWRS Privatization Contractors

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PREFACE

The Department of Energy's (DOE) Richland Operations Office (RL) issued the TWRS Privatization Request for Proposal (RFP) for Hanford Tank Waste Remediation System (TWRS) Privatization in February 1996. Offerors were requested to submit proposals for the initial processing of the tank waste at Hanford. Some of this radioactive waste has been stored in large underground storage tanks at the Hanford Site since 1944. Currently, approximately 56 million gallons of waste containing approximately 240,000 metric tons of processed chemicals and 250 mega-curies of radionuclides are being stored in 177 tanks. These caustic wastes are in the form of liquids, slurries, saltcakes, and sludges. The wastes stored in the tanks are defined as high-level radioactive waste (10 CFR Part 50, Appendix F) and hazardous waste (Resource Conservation and Recovery Act).

Under the privatization concept, DOE will purchase waste treatment services from a contractor-owned, contractor-operated facility under a fixed-price contract. DOE will provide the waste feedstock to be processed but maintain ownership of the waste. The contractor must: a) provide private financing; b) design the equipment and facility; c) apply for and receive required permits and licenses; d) construct the facility and bring it on-line; e) operate the facility to treat the waste according to DOE specifications; and f) deactivate the facility.

The TWRS Privatization Program is divided into two phases, Phase I and Phase II. Phase I is a proof-of-concept/commercial demonstration-scale effort the objectives of which are to a) demonstrate the technical and business viability of using privatized contractors to treat Hanford tank waste; b) define and maintain adequate levels of radiological, nuclear, process, and occupational safety; c) maintain environmental protection and compliance; and d) substantially reduce life-cycle costs and time required to treat the tank waste. The Phase I effort consists of two parts: Part A and Part B.

Part A consists of a twenty-month development period to establish appropriate and necessary technical, operational, regulatory, business, and financial elements. This will include identification by the TWRS Privatization Contractors and approval by DOE of appropriate safety standards, formulation by the Contractors and approval by DOE of integrated safety management plans, and preparation by the Contractors and evaluation by DOE of initial safety assessments. Of the twenty-month period, sixteen months will be used by the Contractors to develop the Part-A products and four months will be used by DOE to develop views, for input into DOE's Part B Contractor selections, of the Contractors' ability to implement integrated safety management and evaluate Contractor products developed under integrated safety management.

Part B consists of a demonstration period to provide tank waste treatment services by one or more of the TWRS Privatization Contractors who successfully complete Part A. Demonstration will address a range of wastes representative of those in the Hanford tanks. Part B will be 10 to 14 years in duration. Within Part B, wastes will be processed during a 5- to 9-year period and will result in treatment of 6 to 13 percent of the Hanford tank waste.

Phase II will be a full-scale production phase in which the remaining tank waste will be processed on a schedule that will accomplish removal from all single-shelled tanks by the year 2018. The objectives of Phase II are to a) implement the lessons learned from Phase I; and b) process all tank waste into forms suitable for final disposal.

A key element of the TWRS Privatization Contracts is DOE regulation of radiological, nuclear, and integrated safety through the establishment of a specifically chartered, dedicated Regulatory Unit (RU) at RL. This regulation by the RU is authorized by the document entitled Policy for Radiological, Nuclear, and Process Safety Regulation of TWRS Privatization Contractors (referred to as the Policy) and implemented through the document entitled *Memorandum of Agreement for the Execution of Radiological, Nuclear, and Process Safety Regulation of The TWRS Privatization Contractors* (referred to as the MOA). The Policy is signed by the Under Secretary of Energy; the Manager, DOE Richland Office (RL); the Assistant Secretary for Environment, Safety and Health (ASEH); and the Assistant Secretary for Environmental Management (ASEM). The MOA is signed by the Manager, RL; the ASEH; and the ASEM. The nature and characteristics of this regulation are also specified in these documents. The MOA details certain interactions among RL, the ASEH, and the ASEM as well as their respective roles and responsibilities for implementation of the DOE regulating program.

The authority of the RU to regulate the TWRS Privatization Contractors is derived from the terms of the TWRS Privatization Contracts. Its authority to regulate the Contractors on behalf of DOE is derived from the Policy. The nature and scope of this special regulation (in the sense that it is based on terms of a contract rather than formal regulations) is delineated in the MOA, the TWRS Privatization Contracts, and the four documents (listed below), from the MOA, which are incorporated into the Contracts. This special regulation by the RU in no way replaces any legally established external regulatory authority to regulate in accordance with their duly promulgated regulations nor relieves the Contractors from any obligations to comply with such regulations or to be subject to the enforcement practices of the regulatory authority.

The Policy, the MOA, the TWRS Privatization Contracts, and the four documents incorporated in the Contracts define the essential elements of the regulatory program, which will be executed by the RU and to which the TWRS Privatization Contractors must conform. The four documents from the MOA incorporated in the Contracts are:

> *Concept of the DOE Regulatory Process for Radiological, Nuclear, and Process Safety for TWRS Privatization Contractors (Regulatory Concept)*, DOE/RL-96-0005,
>
> *DOE Regulatory Process for Radiological, Nuclear, and Process Safety for TWRS Privatization Contractors (Regulatory Process*), DOE/RL-96-0003,
>
> *Top-Level Radiological, Nuclear, and Process Safety Standards and Principles for TWRS Privatization Contractors (Top-Level Standards)*, DOE/RL-96-0006, and
>
> *Process for Establishing a Set of Radiological, Nuclear, and Process Safety Standards and Requirements for TWRS Privatization (Standards Identification Process),* DOE/RL-96-0004.

In the execution of the regulatory program, the RU will consider not only the approaches and practices of DOE but also the regulatory principles and concepts of the Nuclear Regulatory Commission (NRC). The Policy states that

> "It is DOE's policy that TWRS privatized contractor activities be regulated in a manner that assures adequate radiological, nuclear, and process safety by application of regulatory concepts and principles consistent with those of the Nuclear Regulatory Commission."

To this end, the RU will interact with the NRC (under the provisions of a memorandum of understanding with the NRC) during development of regulatory guidance and during execution of the regulatory program to ensure implementation of this policy.

All documents issued by the Office of Radiological, Nuclear, and Process Safety Regulation for TWRS Privatization Contractors are available to the public through the DOE/RL Public Reading Room at the Washington State University, Tri-Cities Campus, 100 Sprout Road, Room 130 West, Richland, Washington.

Table of Contents

1. Introduction

Under contract, each TWRS Privatization Contractor (Contractor) is required to submit a Standards Approval Package (SAP). An element of the SAP is the Integrated Safety Management Plan (ISMP). The U.S. Department of Energy (DOE) Office of Radiological, Nuclear, and Process Safety Regulation for TWRS Privatization Contractors (Regulatory Unit [RU]), at the Richland Operations Office (RL), will evaluate the ISMP and issue an Evaluation Report with recommendations for approval or disapproval to the Regulatory Official (RO). The evaluation of the ISMP will be an objective, unbiased assessment of the Contractor's information based on the criteria in this guidance document (Guide).

The reviewers should familiarize themselves with this Guide prior to initiating the review. Sections 1 and 2 provide the introduction and purpose of the Guide, respectively. Section 3 describes the review approach. Section 4 identifies the approval criteria. Section 5 describes the acceptability review. Section 6 provides guidance for the detailed review of the ISMP and identifies attributes[1] related to each of the approval criteria. Section 7 outlines considerations for recommending whether the ISMP should be approved or disapproved.

2. Purpose

This Guide incorporates the requirements for submittal of the ISMP in the regulatory documents,[2] which are part of the Contract, and utilizes these sources for instructions to assist the reviewers in their evaluation of the ISMP.

3. ISMP Review Approach

The review approach systematically evaluates the ISMP to formulate a set of detailed conclusions that support an approval or disapproval determination based upon the ISMP approval criteria. The review has two steps: 1) Acceptability Review (a 7-day review to determine whether the ISMP is acceptable for detailed review by the RU) and 2) Detailed Review (a 14-week period culminating in an Evaluation Report). The format for the ISMP is generally left to the discretion of the Contractor as long as the information is clear and complete. When additional information is needed to make a determination, the reviewers will prepare detailed questions for the Contractor.

4. ISMP Approval Criteria

The ISMP approval criteria described in the *Regulatory Process* are:

> "The approval of the Contractor's proposed ISMP will be issued upon determination by the Director of the Regulatory Unit that [the]:
>
> 1) program documented in the ISMP complies with all applicable laws and regulations;
>
> 2) program documented in the ISMP conforms to the top-level radiological, nuclear, and process standards and principles contained in DOE/RL-96-0006;
>
> 3) selected safety management processes documented in the ISMP are standards based and are appropriately tailored to the hazards associated with the Contractor's proposed facility, its operation, and its deactivation;

4) selected safety management processes documented in the ISMP properly and adequately address management of process hazards;

5) program documented in the ISMP contains appropriate features of integrated safety management (i.e., integration among safety, design, and operations interests; integration over the life cycle of the activities; and integration into work planning and performance);

6) interfaces among regulatory regimes are appropriately addressed to ensure that adequate protection is fully achieved;

7) safety documentation processes delineated in the ISMP provide for appropriate document control and maintenance;

8) scheduling of the safety-related activities as described in the ISMP, including generation of regulatory submittals, [sic];[3]

9) self-assessment elements documented in the ISMP are appropriate; and

10) safety definition, implementation, and maintenance roles, responsibilities, and authorities defined in the ISMP are clear and appropriate."[4]

5. ISMP Acceptability Review

Introduction

This Guide uses the term "acceptability review" to describe the review of the ISMP for completeness and adequacy. The acceptability review is required by the *Regulatory Process*, which states that the RU shall:

> "Review the Standards Approval submittal package for completeness and adequacy within one week from the day of its receipt."[5]

In performing the ISMP acceptability review, the reviewers determine whether the material is in a form that is reviewable by the RU and incorporates the submittal requirements established in the Contract.[6] If these considerations are satisfied, then the ISMP is acceptable for detailed review. Acceptability for the detailed review does not imply approval of the ISMP.

The reviewers will evaluate each submittal requirement of the ISMP for completeness and adequacy based upon the attributes cited below and document their findings. If the Contractor has generally provided information that addresses each of these attributes, the submittal can be considered complete and adequate. If specified attributes are not addressed, the reviewers will determine whether the missing information is available elsewhere or is needed to conduct the detailed review. It may be appropriate for the Contractor to commit to provide some information at a later date (e.g., Initial Safety Assessment).

Completeness and Adequacy Elements for Each of the ISMP Requirements

5.1 Key Safety-Related Activities

a. Submittal Requirement

"Define the key safety-related activities to be performed by the Contractor."[7]

b. Completeness

Key safety-related program and process activities performed by the Contractor are defined.

c. Adequacy

The basis for the selection of the safety-related program and process activities is described.

5.2 Standards-Based Management Process

b. Submittal Requirement

"Specify the standards-based management processes to be used by the Contractor to ensure that radiological, nuclear, and process safety is adequately defined (i.e., tailored to the nature and level of hazards, including process hazards), implemented, and maintained."[8]

c. Completeness

- The standards-based management processes which will ensure radiological, nuclear, and process safety are specified.
- The tailoring of management processes to the nature and level of the hazard is described.

d. Adequacy

- The basis for the selection of the standards-based management processes to be used is described.
- The rationale for selecting the standard(s) for each standards-based management process is described.
- The rationale for the tailoring of the standards-based management processes to be used is described.

5.3 Compliance with DOE Regulations and the SRD, and Conformance to Top-Level Standards

a. Submittal Requirement

"Ensure that the Contractor is in compliance with DOE Nuclear Safety Regulations, in conformance with the DOE-stipulated top-level safety standards and principles, and in compliance with the SRD."[9]

b. Completeness

- The management processes which ensure compliance with the DOE Nuclear Safety Regulations (10 CFR 830 and 10 CFR 835) and the SRD are described. Conformance with the DOE-stipulated top-level safety

standards and principles are described.

c. Adequacy

- The reviewers should verify that conformance with top-level standards and compliance with nuclear safety regulation and the SRD are described.
- The reviewers verify compliance with 10 CFR 830 includes the submittal of a Quality Assurance Program (QAP) plan and QA implementation plan.

5.4 Regulatory Interfaces

a. Submittal Requirement

"Define the Contractor's interfaces with other regulatory regimes such as environmental protection, occupational safety, and safeguards and security, and define the processes for resolving conflicting requirements at these interfaces and

for ensuring safety adequacy at these interfaces (i.e., ensuring that safety "gaps" do not occur)."[10]

b. Completeness

- The interfaces with other regulatory authorities (e.g., EPA, Ecology, Department of Health, OSHA, Safeguard and Security) are defined.
- The process for resolving conflicting requirements between regulatory authorities and ensuring adequate safety is described.

c. Adequacy

- The basis for the identification of the regulatory interfaces is described.
- The basis for the adequacy of the conflict identification and resolution process is provided.

5.5 Flow and Schedule of Safety-Related Work and Deliverables

a. Submittal Requirement

"Specify the expected flow and schedule of the Contractor's safety-related work and deliverables, including interactions with the Regulatory Unit."[11]

b. Completeness

- The expected flow and schedule of the safety-related work, deliverables, and interactions with the RU are specified.

c. Adequacy

- The basis for the adequacy of flow and schedule of the safety-related work and regulatory actions is provided.

5.6 Assessment Program

a. Submittal Requirement

"Describe the self-assessment functions to be employed by the Contractor."[12]

b. Completeness

- The self-assessment functions are described.

c. Adequacy

- A basis for the adequacy of the self-assessment functions is described.

5.7 Tailoring

a. Submittal Requirement

"Describe the Contractor's approach for tailoring its radiological, nuclear, and process safety deliverables and actions commensurate with the nature and level of hazards associated with its waste processing activities."[13]

b. Completeness

- The approach for tailoring the radiological, nuclear, and process safety deliverables and actions so that they are commensurate with the nature and level of hazards is described.

c. Adequacy

- The rationale for the adequacy of tailoring the safety deliverables and actions to the nature and level of the hazards is provided.

5.8 Roles and Responsibilities

a. Submittal Requirement

"Identify roles, responsibilities, and authorities for defining, implementing, and maintaining safety."[14]

b. Completeness

- The roles, responsibilities, and authorities for defining, implementing, and maintaining safety are identified.

c. Adequacy

- The basis for the roles, responsibilities, and authorities for defining, implementing, and maintaining safety are described. Description of the following should be included: current organization structure, Part B roles and responsibilities, lines of responsibility and authority, and lines of communication.

5.9 Process Safety

a. Submittal Requirement

"The integrated standards-based safety management program shall integrate the appropriate planning and practices elements specified in 29 CFR 1910.119, 'OSHA Process Safety Management of Highly Hazardous Chemicals'."[15]

b. Completeness

- The standards-based safety management program integrates the planning and practices elements specified in 29 CFR 1910.119 (Hazards Analysis, Control of Subcontractors, Change Management, and Compliance Audits).

c. Adequacy

- The ISMP describes how the pertinent 29 CFR 1910.119 elements have been incorporated into the standards-based safety management program. ("Pertinent" as used here recognizes that 10 CFR 1910.119 applies when the quantity of the hazardous chemical exceeds a level specified by the regulation.)

In areas where additional information is required to evaluate the submittal, requests for additional information will be generated. Upon completing the review, the RO will issue a letter to the Contractor regarding the acceptability of the package. If the package is rejected, the RO will provide a list of the reasons for the rejection. After the package is accepted for review, the RU may request additional information from the Contractor to clarify the submittal.

6. ISMP Detailed Review

6.1 Review of Compliance to Laws and Regulations

Introduction

This section provides the reviewers with criteria to assess the adequacy of the management processes that will be used to ensure compliance with laws and regulations. Applicable laws and regulations include those laws and regulations which DOE has enforcement jurisdiction that relate to radiological, nuclear, and process safety. At present, there are two regulations which apply to the Contractors: 10 CFR 830 and 10 CFR 835.

This review is divided into two areas: 1) the measures taken to ensure compliance with applicable laws and regulations and 2) the QAP and QA implementation plans.

a. Approval Criterion

"The program documented in the ISMP complies with all applicable laws and regulations."[16]

b. Review

This review consists of the following actions:

- Evaluates the ISMP to confirm the appropriateness of the laws and regulations identified by the Contractor as applicable to its integrated safety management processes.
- Evaluates the adequacy of Contractor management processes to ensure compliance with laws and regulations that may change or come into

effect during the project life cycle.

- Reviews the ISMP's list of key safety-related activities and evaluates the need for the Contractor to consider and include the effects of additional laws and regulations not included in the SRD.
- Determines if the ISMP incorporates a process to ensure compliance with 10 CFR 830 and 10 CFR 835.*

c. Attributes

Attribute 1 - Statutory Compliance

The ISMP complies with 10 CFR 830 and 10 CFR 835 and has included provisions in its ISMP to ensure compliance.

The reviewers should assess if the Contractor has committed to review new requirements to determine their applicability to the Contractor's TWRS operations, to identify any required changes to the authorization basis, to propose a plan to implement those changes, and to obtain acceptance of the plan by the RU in the event that additional applicable laws or regulations are promulgated.[17]

Attribute 2 - Compliance with 10 CFR 830.120

The Contractor's QAP and QA implementation plan complies with 10 CFR 830.120. Specific guidance for this review is provided in the *Guidance for Review of TWRS Privatization Contractor's Initial Quality Assurance Program*, RL/REG-96-01, Revision 0. The reviewers should also determine if the QA implementation plan fulfills the QAP.

Attribute 3 - Compliance with 10 CFR 835

The Contractor has described its commitment and management process to ensure compliance with 10 CFR 835.

The Contractor has included provisions in its integrated safety management program to appropriately define, document, secure approval, and implement the elements of 10 CFR 835 to ensure compliance.

The Contractor has included provisions in its integrated safety management program to implement the Radiation Protection Practices (RPP) required by 10 CFR 835.101. A commitment to updating the RPP as required throughout the facility life cycle should be included.

6.2 Review of Conformance to Top-Level Safety Standards and Principles

Introduction

This review addresses the adequacy of the ISMP conformance with top-level standards and principles as they apply to the management processes.

a. Approval Criterion

*This list may change as regulations are revised.

"The program documented in the ISMP conforms to the top-level radiological, nuclear, and process safety standards and principles contained in DOE/RL-96-0006."[18]

b. Review

This review determines if the ISMP conforms with all the top-level standards and principles of DOE/RL-96-0006. For the top-level standards and principles that do not have specific attributes, the reviewers should determine that the ISMP describes how a process will ensure conformance with the selected standard or principle.

c. Attributes

Attribute 1 - Defense-in-Depth

The ISMP has provisions in the safety management processes described to ensure the defense-in-depth principle is incorporated. ISMP defense-in-depth provisions should address:

- The manner in which the Contractor intends to vest safety in multiple, independent safety provisions so that no one provision is relied upon excessively to protect the public, the workers, or the environment.
- How defense-in-depth features will be tailored in a manner commensurate with identified hazards.[19]

The reviewers should evaluate the ISMP and determine if the Contractor's approach to facility safety addresses:

- Prevention of accidents.[20]
- Control of normal operations.[21]
- Retention of radioactive material through a conservatively designed confinement system.[22]
- Reliance on automatic systems that would be used to place and maintain the facility in a safe state and limit the potential spread of radioactive materials when operating conditions exceed predetermined safety setpoints.[23]

Attribute 2 - Safety Responsibilities

The reviewers should verify that the ISMP:

- Establishes the Contractor's assumption of primary safety responsibility for the facility.[24]
- Describes processes to obtain, analyze, and implement lessons learned from relevant research, design, operation, construction, modification, and operation of similar facilities.

Attribute 3 - Authorization Basis

The ISMP establishes an adequate definition of the authorization basis material, as well as a commitment for keeping it current.

The material identified as part of the authorization basis should include the following:

- ISMP and SRD.
- Safety analysis.
- Design specifications and drawings.
- Technical Safety Requirements related to all safety-related structures, systems, and components.
- All other materials upon which the Contractor intends to rely for receiving authorization to proceed to construction, operation, or deactivation or submit to regulatory oversight.[25]

The commitment to maintan the authroization basis current should include:

- A description of the process that will be used to evaluate and implement changes to the authroization basis.
- A definition of “current” that establishes a maximum length of time that may elapse in updating the authroization basis to reflect relevant new or reivsed information.

Attribute 4 - Safety/Quality Culture

The ISMP contains provisions to establish an appropriate safety and quality culture that includes an emphasis on excellence in all activities.[26]

Attribute 5 - Quality Assurance Program (QAP)

The QAP and QA implementation plans are expected to be submitted as part of the ISMP. The review of the QAP is described in Section 6.1. The reviewers should verify that sufficient detail is provided in the ISMP to conclude that the QAP is adequately integrated into the safety management programs described in the ISMP.

Attribute 6 - Facility Design for Postulated Events

The ISMP describes the facility design process and that the design process provides assurance that the facility is designed for the set of events that includes the following:

- Normal Operations.
- Anticipated Operational Occurrences.
- Postulated accidents including external events.

The ISMP incorporates appropriate methodologies for the following analysis activities for the above set of events in the facility design process:

- Risk assessment.
- Safety analysis.

Attribute 7 - Proven Engineering Practices

The reviewers should evaluate whether provisions of the ISMP describe the method by which the Contractor will identify and incorporate safety technologies into the facility design.

The selected method should ensure that the technologies are proven by experience or testing and are reflected in approved codes and standards. If the Contractor proposes using new design features, the reviewers should determine if the ISMP has described the research, modeling or prototype testing that will take place in order to ensure that the technology can be relied upon for safety.

The reviewers should also verify that the following are addressed:

- Prevention of common-cause or common-mode failure.
- Safety system qualification.
- Supplement codes and standards as necessary to address facility specific conditions.

Attribute 8 - Criticality Safety

The implementation of the nuclear criticality safety program is described.

Attribute 9 - Radiation Protection Practices

The ISMP describes the process to ensure adequate radiation protection practices are followed in the design, construction, and pre-operational testing phases of the facility.[27] The ISMP should contain provisions to ensure that during the design stage the radiation protection features are implemented to protect workers from radiation exposure and keep emissions of radioactive effluents As Low as Reasonably Achievable (ALARA) and within prescribed limits.

The reviewers should consider the manner in which the Contractor intends to incorporate those features at the design stage,[28] as well as the manner in which the Contractor's design of the facility will incorporate those same provisions in the deactivation and final decommissioning of the facility. The objective should be to both minimize radiation exposures to occupational workers, co-located workers, and the public during and following deactivation and decommissioning activities, as well as to minimize the quantity of radioactive waste.[29]

Attribute 10 - Emergency Preparedness

The ISMP contains adequate provisions to ensure that an Emergency Preparedness Plan is provided and includes the following :

- Anticipated emergency response interfaces with other co-located facilities at the Hanford Site and with local authorities.
- Response capabilities that will be provided by the Contractor.
- Training.
- Emergency exercises.
- Additional capability to place and maintain the facility in a safe state following an accident if the normal control areas are expected to become uninhabitable.
- Anticipated emergencies to be considered in emergency preparedness.

Attribute 11 - Safety Systems Design

The ISMP includes adequate provisions to address the following for the design

of safety-related systems:

- The use of highly reliable means to accomplish safety functions, including design features that enhance the margins of safety through simplified, inherent, passive, or other highly reliable means to accomplish safety functions.
- Hierarchy of reliance upon various means to accomplish safety functions (e.g., reliance upon engineered controls is preferred to reliance upon administrative controls).

Attribute 12 - Human Factors

The ISMP contains adequate provisions to ensure human factors are properly addressed in the design and operations of the facility. The human factors' provisions should address the following elements:

- Measures to mitigate the possibility for human error.
- Systems design to facilitate correct decisions by operators and inhibit wrong decisions.
- Measures to detect and correct and/or compensate for human errors.
- Provisions of instrumentation and control capability sufficient to allow operators to diagnose faulty conditions, to place and maintain the facility in a safe state, and to mitigate accidents.
- Parameters to be monitored in the control room and their placement to ensure clear and unambiguous indications of facility status.

Attribute 13 - Reliability, Availability, Maintainability, and Inspectability (RAMI)

The ISMP includes adequate provisions for a RAMI program that:

- Assigns reliability targets to safety-related structures, systems, and components.
- Designates, designs, and constructs safety-related structures, systems, and components for appropriate inspection, testing, and maintenance throughout their operating lives to verify their continued acceptability for service with an adequate safety margin.

Attribute 14 - Pre-Operational Testing and Operation

The ISMP contains provisions for pre-operational testing and operations. Adequate time and resources should be devoted to cold- and hot-testing phases prior to initial production to demonstrate the facility functions as intended and to establish data on the performance of safety-related structures, systems, and components.

Attribute 15: Training and Qualification[30]

The ISMP provides for a training and qualification plan that contains the following provisions:

- Personnel engaged in safety-related activities will be trained and qualified to perform their duties.[31]

- Operators are trained and retrained in the procedures for conditions that exceed the design basis of the facility.[32]
- Continual training of operations and maintenance personnel.[33]

Attribute 16 - Internal Safety Oversight

The ISMP adequately provides for the following elements of internal safety oversight:

- The definition and description of Safety Review Organizations that are responsible for ensuring the safety of the facility.
- The establishment of separation between the responsibilities of the Safety Review Organizations and those of other organizations so that their independence is retained.[34]
- The identification of the qualifications of internal safety oversight personnel.

The reviers should verify that the ISMP adequately provides for the resolution of any Unresolved Safety Questions (USQ).[35]

6.3 Review of Standards-Based Management

Introduction

This segment of the review verifies that the safety management processes are described in terms of appropriate standards and tailored according to the risk associated with the activities. Tailoring is the process that establishes the level of control commensurate with the significance of the hazard.

a. Approval Criteria

"The selected safety management processes documented in the ISMP are standards based and are appropriately tailored to the hazards associated with the Contractor's proposed facility, its operation, and its deactivation."[36]

b. Review

The reviewers should perform the following actions:

- Review the description of the facility and the waste-treatment processes to provide the basis for understanding the safety-related programmatic activities that must be accomplished and their relationship to hazards control.
- Review the descriptions of the safety-related programmatic activities (e.g. design, fabrication, testing, operations, maintenance, training, and quality assurance).
- Determine if the set of activities is complete enough to provide a sufficient basis for defining the safety management processes, associated hazards, and appropriate tailoring.
- Evaluate the adequacy of the types of safety management processes and associated standards to control the hazards.
- Determine if the selected safety management processes are standards-

based and have been tailored to the hazards.

c. Attributes

Attribute 1 - Safety Management Processes

The reviewers should review the description of the safety management processes to ensure that the safety standards and requirements of the SRD will be implemented and maintained.

The reviewers should determine if these selected safety management processes adequately address the safety-related programmatic activities and safety management requirements of the Contract.

The reviewers should determine if the safety management processes are standards-based. (Standards for this purpose are defined as the "expressed expectations for the performance of work.") Based on this definition, the Contractor has latitude in defining standards.

Attribute 2 - Tailoring Safety Management Processes

The ISMP ensures that safety management processes are appropriately tailored to the hazards associated with the proposed facility and its design, construction, testing, operation, and deactivation.

The ISMP includes a description of the methods used to tailor safety-related programmatic activities. For example, the level of rigor for the control of activities can be tailored through level of detail in procedures, level of qualification and training required, depth and detail of governing standards, and the degree of use of other conduct of operations controls. Other methods of tailoring are also acceptable provided the rationale for their use is clearly described and relies on the significance of the hazards as the principal criteria.

The reviewers should evaluate the proposed method for revising the tailoring of the safety management processes as the nature of the activities change, additional information relating to the hazards becomes available, or the waste treatment processes change.

6.4 Review of Process Safety Management

Introduction

This segment of the review evaluates the adequacy of the integration of the appropriate planning and practice elements specified in 29 CFR 1910.119 and process safety management principles.

a. Approval Criterion

"The selected safety management processes documented in the ISMP properly and adequately address management of process hazards."[37]

b. Review

The reviewers should determine if the ISMP describes any facility process that

is subject to the requirements of 29 CFR 1910.119. If a process is identified, the reviewers should verify that the ISMP integrates the appropriate planning and practice elements of 29 CFR 1910.119.

The reviewers should determine if the ISMP conforms to the top-level process safety management principles. The reviewers should determine if there is reasonable confidence that proper execution of the ISMP will result in compliance with Section 5.0 of DOE/RL-96-0006, as outlined in the following attributes.

c. Attributes

Attribute 1 - Process Safety Information

The ISMP addresses the development and maintenance of information that provide a foundation for identifying and understanding the process hazards.

The ISMP should provide a description of process safety information which should include the following:

- A summary of material data.
- A description of each process and its operation.
- Equipment design data.

The ISMP should provide the information necessary to confirm that 1) the process safety equipment is appropriate for the process operation, 2) the equipment's integrity is maintained, and 3) the equipment meets codes and standards.[38]

Attribute 2 - Control of Subcontractors

The ISMP provides for the control of subcontractors including provisions for informing subcontractors of potential hazards related to the subcontractor's work and ensuring that subcontractors provide their workers with the appropriate procedures and training necessary for performing their jobs safely.[39]

Attribute 3 - Change (Configuration) Management

The reviewers should verify that the Contractor has evaluated all planned changes involving the technology of the process and the facility design and operation. The reviewers should determine if the Contractor has established provisions for facility changes involving process chemicals, technology, equipment, and procedures. The procedures which describe change management should address the technical basis for the proposed changes, impact of the changes on process safety, modification of the operating procedures, the schedule for proposed changes, and authorization for proposed changes.[40]

Attribute 4 - Compliance Audits

The ISMP contains commitments to periodically conduct audits to certify that the procedures and practices developed under the process safety management program are adhered to and are adequate, as well as to determine and document appropriate responses to each audit findings.

Attribute 5 - Process Hazards Analysis

The ISMP adheres to acceptable industry practices to perform hazards analysis. The hazards analysis process should provide for performing and documenting hazards analysis that address the following elements:

- The selected hazards analysis process is tailored.
- The hazards analysis process considers the effects of engineering and administrative controls, human factors, facility siting, and previous incidents in the hazard analysis.
- The hazards analysis process requires documentation of the results of the hazards analysis including process hazards and possible safety and health effects.
- The hazards analysis process requires submitting the results of the hazards analysis to the Regulatory Official for evaluation and in support of authorization decisions and regulatory oversight.

Attribute 6 - Conformance to Other Top-Level Safety Standards and Principles

The Contractor has addressed the following principles or has at least provided a placeholder for update when the ISMP is reviewed again at Authorization of Construction and Operation.

- The ISMP addresses the development of operating procedures to provide clear instructions. The procedures should address the following elements: operating phase of the process, operating limits, safety and health considerations, and safety systems and their functions.[41]
- The ISMP contains a commitment to review and update the hazard analysis periodically.[42]
- The ISMP contains a commitment to develop and implement an operator training program that includes the following elements: an overview of the facility processes and operating procedures; the specific safety and health hazards, operating limits, emergency operations, and safety work practices; and refresher training.[43]
- The ISMP contains a commitment to perform a Pre-Startup Review of the facility.[44]
- The ISMP contains a commitment to implement a mechanical integrity program that includes: 1) written procedures, 2) training for maintenance activities, 3) inspection and performance testing of process equipment, 4) quality assurance measures, and 5) measures to correct deficiencies in equipment that are outside acceptable limits.
- The ISMP contains a commitment to implement a process to control Hot Work operations performed in or near the process or facility.[45]
- The ISMP contains a commitment to investigate incidents.[46]
- The ISMP contains a commitment to address an emergency action plan.[47]

6.5 Review of Integrated Safety Management

Introduction

This segment of the review determines if the Contractor's safety management program is integrated.

a. Approval Criterion

"The program documented in the ISMP contains appropriate features of integrated safety management (i.e., integration among safety, design, and operations interests; integration over the life cycle of the activities; and integration into work planning and performance)."[48]

b. Review

The reviewers should utilize the attributes listed below in making a determination with regard to integration of the ISMP.

c. Attributes

Attribute 1 - Integration into Work Planning and Performance

The ISMP is consistent with the guiding principles and **core safety management functions** (see below) of integrated safety management. These guiding principles are:

- Line Management is responsible for the protection of the pubic, the workers, and the environment.
- Clear, unambiguous lines of authority and responsibility for ensuring safety are established and maintained at all organizational levels.
- Personnel possess the experience, knowledge, skills, and abilities necessary to discharge their responsibilities.
- Resources are effectively allocated to address safety, programmatic, and operational considerations. Protecting the public is a priority whenever activities are planned and performed.
- Before work is performed, the associated hazards are evaluated and an agreed-upon set of standards and requirements are established which, if properly implemented, provide adequate assurance that the public, the workers, and the environment are protected from adverse consequences.
- Administrative and engineering controls to prevent and mitigate hazards are tailored to the work and associated hazards being performed.
- The operational conditions and requirements are clearly established and agreed-upon.

The following are the **core safety management functions**:

- Define the scope of work.
- Identify and analyze the hazards associated with the work.
- Develop and implement hazard controls.
- Perform the work within the controls.
- Provide feedback on the adequacy of the controls and continuous improvements in defining and planning the work.

6.6 Review of Regulatory Interfaces

Introduction

This segment of the review ensures that adequate radiological, nuclear, and process safety is achieved at regulatory interfaces where conflicting conditions or requirements could exist.

a. Approval Criterion

"The interfaces among regulatory regimes are appropriately addressed to ensure that adequate protection is fully achieved."[49]

b. Review

The reviewers should determine if the Contractor has identified how regulatory interface conflicts will be evaluated in order to protect workers, the public, and the environment. For example, a plant shutdown due to an environmental violation could lead to the settling of fissile material, posing a criticality problem.

The reviewers should determine if the Contractor has defined an adequate approach for resolving such conflicts without degradation of required safety.

c. Attributes

Attribute 1 - Environmental Protection Interface

The ISMP explains the Contractor's interaction with the EPA, the Washington State Department of Ecology, the Washington State Department of Health, and the Benton County Clean Air Authority to anticipate and avoid safety problems arising from considerations other than radiological, nuclear, and safety regulation.

Attribute 2 - Occupational Health and Safety Interface

The ISMP explains the Contractor's interaction with occupational, safety, and health regulators to anticipate and avoid safety problems arising from considerations other than radiological, nuclear, and safety regulation.

Attribute 3 - Safeguards and Security Interface

The ISMP explains the Contractor's interaction with the safeguards and security oversight organization to anticipate and avoid safety problems arising from considerations other than radiological, nuclear, and safety regulation.

Attribute 4 - Resolution of Conflicting Requirements and Standards

The ISMP has described the provisions to identify and resolve conflicts, while ensuring safe operation when potential conflicts arise between safety and compliance with other regulatory requirements (and among the other requirements).

6.7 Review of Document Control and Maintenance

Introduction

This segment of the review determines if the Contractor has established a document control and maintenance program and verifies that documents developed under the safety management processes are controlled under the Contractor's QAP.

a. Approval Criterion

"Safety documentation processes delineated in the ISMP provide for appropriate document control and maintenance."[50]

b. Review

The document control and maintenance process should be based on the overall QAP and QA implementation plans. The review of the Contractor's QAP is described in Section 6.1.

The reviewers should verify that the ISMP is included within the scope of documents subject to the document controls of the QAP and the integrated safety management processes described require that safety documentation be subject to the document controls of the QAP.

6.8 Review Scheduling of Safety-Related Activities

Introduction

This segment of the review ensures that the Contractor's safety-related activities are consistent in terms of work flow and support the major RU regulatory actions.

a. Approval Criteria

"Scheduling of the safety-related activities as described in the ISMP, including generation of regulatory submittals, is consistent with Figure 2 of [the *Regulatory Process*]."[51]

b. Review

The reviewers should determine if sufficient planning information is provided so that related RU responsibilities can be anticipated, budgeted, and planned.

c. Attributes

Attribute 1 - Scheduling Safety-Related Activities

The reviewers should determine if schedule information of relevance to the RU is adequate. Scheduling of the safety-related activities include the development of regulatory submittals and should be consistent with Figure 2 of the *Regulatory Process* (DOE/RL-96-0003) and should include major milestones.

The reviewers should determine if the Contractor has provided an adequate schedule time-line including elements related to design, construction, operation, and deactivation.

The reviewers should determine whether a commitment to the schedule has been made and if the Contractor has presented evidence of its ability to meet the schedule.

Attribute 2 - Schedule for Regulatory Submittals

The Contractor has provided adequate schedule detail which addresses submittals (conforming to Figure 2 of DOE/RL-96-0003) for the following:

- Initial Safety Assessment

- Construction Authorization Request Package, including the Preliminary Safety Analysis Report (PSAR)
- Operating Authorization Request Package, including the Final Safety Analysis Report (FSAR)
- Assessment and Reporting during operation
- Deactivation Authorization Request.

Attribute 3 - Flow of Safety-Related Work and Deliverables

The interdependencies of deliverables are acceptably detailed.

The reviewers should determine if the flow of safety-related work and the flow of the resulting information (e.g., hazards analysis at a time during which the design can be influenced) is timely and relevant to the design process and to construction milestones.

6.9 Review of Self-Assessment

Introduction

This segment of the review evaluates the adequacy of the Contractor's measures to establish acceptable self-assessment processes.

a. Approval Criteria

"Self-assessment elements documented in the ISMP are appropriate."[52]

b. Review

The Contractor's self-assessment process should be part of or based on the QAP and QA implementation plan. Note that self-assessment relates to Criterion 3, "Quality Improvement" (10 CFR 830.120[c][I][iii]), and Criterion 10, "Independent Assessment" (10 CFR 830.120[c][3][ii]), of the DOE Quality Assurance Rule. The Contractor may have chosen to integrate the information required to meet this approval criterion into its QAP. For this part of the review, the reviewers should confirm that the QA review adequately addressed self-assessment. Alternatively, if the RU's QA review did not adequately address self-assessment, the reviewers should evaluate the Contractor's submittal against this criterion.

6.10 Review of Organizational Roles, Responsibilities and Authorities

Introduction

This segment of the review assesses the adequacy of the integrated safety management program provisions to ensure that responsibilities, roles, and authorities are established for the performance of programmatic activities related to definition, implementation, and maintenance of safety.

a. Approval Criteria

"Safety definition, implementation, and maintenance roles, responsibilities, and authorities defined in the ISMP are clear and appropriate."[53]

b. Review

The Contractor's safety definition, implementation, and maintenance roles, responsibilities, and authorities should be part of or based upon the QAP and QA implementation plan. Note that safety definition, implementation, and maintenance roles, responsibilities, and authorities relates to Criterion I, "Quality Improvement," (10 CFR 830.120(c)(1)(l). The Contractor may have chosen to integrated the information to meet this approval criterion into its QAP. The reviewers should confirm that the RU's review adequately addresses these items. Alternatively, if the RU's QAP review did not adequately address these items, the reviewers should evaluate the Contractor's submittal against this criterion.

7. ISMP Approval or Disapproval

a. Approval

To recommend approval of the ISMP to the Regulatory Official, the reviewers must conclude that the Contractor has met all of the approval criteria. The process by which technical differences of opinion are resolved among the reviewers is described in the Review Team charter. The assessment of the Review Team will be thoroughly documented, including the method used to come to the approval determination and the elements considered in reaching the decision. The Review Team may recommend approval contingent upon the submittal of additional information from the Contractor by a specified date.

b. Disapproval

To recommend disapproval of the ISMP to the Regulatory Official, the Review Team must conclude that the Contractor has failed to meet one or more of the approval criteria. The RU will provide the Contractor with a clear, written explanation of the areas of the ISMP submittal which failed to meet the approval criteria.

8. Abbreviations

ALARA	As Low as Reasonable Achievable
CFR	Code of Federal Regulation
CM	Configuration Management
DOE	Department of Energy
EPA	Environmental Protection Agency
FSAR	Final Safety Analysis Report
ISA	Initial Safety Assessment
ISMP	Integrated Safety Management Plan
NRC	Nuclear Regulatory Commission
OSHA	Occupational Safety and Health Administration
PSAR	Preliminary Safety Analysis Report
QA	Quality Assurance

QAP Quality Assurance Program

RAMI Reliability, Availability, Maintainability, and Inspectability

RFP TWRS Privatization Request for Proposal

RL Richland Operations Office

RPP Radiation Protection Practices

RU Office of Radiological, Nuclear, and Process Safety Regulation (Regulatory Unit)

SAP Standards Approval Package

SRD Safety Requirements Document

SSC Structures, Systems, and Components

TWRS Hanford Tank Waste Remediation System

USQ Unresolved Safety Questions

9. Glossary

Administrative Controls. Provisions relating to organization and management, procedures, record keeping, assessment, and reporting necessary to ensure safe operation of a facility.

Authorization Agreement. The document mutually agreed upon by the Director of the Regulatory Unit and a regulated Contractor that specifies authorization terms and conditions.

Core Safety Management Functions. Define the scope of work; identify and analyze the hazards associated with the work; develop and implement hazard controls; perform the work within the controls; and provide feedback on the adequacy of the controls and continuous improvements in defining and planning the work.

Design.[54] The process and the result of developing the concept, detailed plans, supporting calculations and specifications for a nuclear facility and its parts.

Document. Document means recorded information that describes, specifies, reports, certifies, requires, or provides data or results. A document is not considered a record until it meets the definition of record.

Guide. This document.

Hazard Evaluation. The analysis of the significance of hazardous situations associated with a process or activity. Uses qualitative techniques to pinpoint weaknesses in the design and operation of facilities that could lead to accidents.[55] Hazard Evaluation techniques include HAZOP Analysis, Fault and Event tree analysis and other methods.

Item. Item is an all-inclusive term used in place of any of the following: appurtenance, assembly, component, equipment, material, module, part, structure, subassembly, subsystem, system, unit, or support systems.

Process. (Related to Quality Assurance) A series of actions that achieves an end or result.

Process Element. A component, subsystem, system, or region within of the facility.

Each Contractor may define different process elements when performing their hazards evaluations.

Quality. The condition achieved when an item, service, or process meets or exceeds the user's requirements and expectations.

Quality Assurance. All those actions that provide confidence that quality is achieved.

Quality Assurance Program. The overall program established to assign responsibilities and authorities, define policies and requirements, and provide for the performance and assessment of work.

Record. A completed document or other media that provides objective evidence of an item, service, or process.

Regulatory Official. Director of the Regulatory Unit.

Regulatory Unit. The organization reporting to the Regulatory Official dedicated to supporting the Regulatory Official in executing regulatory authority.

Related Submittal Requirement.

Service. The performance of work, such as design, construction, fabrication, inspection, nondestructive examination/testing, environmental qualification, equipment qualification, repair, installation, or the like.

Standards Approval Package. The combined SRD and the ISMP packages.

Submittal Requirement. Information required of the Contractors under the authority of the TWRS Privatization Contracts, and the four documents incorporated in the Contracts.

Tailoring. A process by which the level of analysis, documentation, and actions necessary to comply with a requirement are commensurate with:

1) The relative importance to safety, safeguards, and security;

2) The magnitude of any hazard involved;

3) The life cycle stage of a facility;

4) The programmatic mission of a facility;

5) The particular characteristics of a facility; and

6) Any other relevant factor.

ENDNOTES

1. "Attributes" are not Contract requirements, but are elaboration's on requirements generated by the RU.

2. *Concept of the DOE Regulatory Process for Radiological, Nuclear, and Process Safety for TWRS Privatization Contractors (Regulatory Concept),* DOE/RL-96-0005,

   DOE Regulatory Process for Radiological, Nuclear, and Process Safety for TWRS Privatization Contractors (Regulatory Process), DOE/RL-96-0003,

   Top-Level Radiological, Nuclear, and Process Safety Standards and Principles for TWRS Privatization Contractors (Top-Level Standards), DOE/RL-96-0006, and

   Process for Establishing a Set of Radiological, Nuclear, and Process Safety Standards and Requirements for TWRS Privatization (Standards Identification Process), DOE/RL-96-0004.

3. Removed reference to Figure 2 in the *Regulatory Process*, p. 26, which describes the schedule for the overall program, beginning with Contract Award and ending in Deactivation.

4. *Regulatory Process*, Section 3.3.1.

5. *Ibid*, Section 4.1.3, item 3.

6. *Ibid*, Section 4.1.2, items 11-15.

7. *Ibid*, , item 11(a).

8. *Ibid*, item 11(b).

9. *Ibid*, item 11(c).

10. *Ibid*, item 11(d).

11. *Ibid*, item 11(e).

12. *Ibid*, item 11(f).

13. *Ibid*, item 11(g).

14. *Ibid*, item 11(h).

15. Contract, Part 1, Section C, Standard 4, paragraph 6, p.C-2 2.

16. *Regulatory Process*,Section 3.3.1.

17. If the SRD Guidance does not identify specific statutes, it may be appropriate to call them out here. (e.g., RCRA, CAA, EPCRA, CWA, etc.).

18. *Ibid*, item 2.

19. *Top-Level Standards and Principles*, Section 4.1.1.1.

20. *Ibid*, Section 4.1.1.2.

21. *Ibid*,, Section 4.1.1.3.

22. *Ibid*, Section 4.1.1.4.

23. *Ibid*, Section 4.1.1.5.

24. *Ibid*, Section 4.1.2.1, p. 7.

25. *Ibid*, Section 4.1.3.1, p. 7.

26. *Ibid*, Section 4.1.4.1, p. 7.

27. *Ibid*, Section 4.2.3.1.

28. *Ibid*, Section 4.2.3.2.

29. *Ibid*, Section 4.2.3.3.

30. *Ibid*, Section 4.3.4.

31. *Ibid*, Section 4.3.4.1.

32. *Ibid*, Section 4.3.4.3.

33. *Ibid*, Section 4.3.4.2.

34. *Ibid*, Section 4.4.1.

35. *Ibid*, Section 4.4.4

36. *Regulatory Process*, Section 3.3.1.

37. *Ibid*, Section 3.3.1, item 4.

38. *Top-Level Standards and Principles*, Section 5.2.1.

39. *Ibid*, Section 5.2.5.

40. *Ibid*, Section 5.2.9.

41. *Ibid*, Section 5.2.3.

42. *Ibid*, Section 5.2.2.

43. *Ibid*, Section 5.2.4.

44. *Ibid*, Section 5.3.6.

45. *Ibid*, Section 5.2.8.

46. *Ibid*, Section 5.2.10.

47. *Ibid*, Section 5.2.11.

48. *Regulatory Process*, Section 3.3.1, item 5.

49. *Ibid* , item 6.

50. *Ibid*, item 7.

51. The Figure referred to is in *Regulatory Process*, p. 26, which describes the schedule for the overall program, beginning with Contract Award and ending in Deactivation.

52. *Regulatory Process*, Section 3.3.1, item 9.

53. *Ibid*, item 10.

54. Derived from the definition of design used in IAEA Code on the Safety of Nuclear Power Plants: Quality Assurance, 50-C-QA (Rev. 1).

55. AIChE Guidelines, p. xxv.